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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/734,274	Applicant(s) MULDER, KAREL HERO	
	Examiner HELEN NGUYEN	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 May 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23-30,32-35 and 39-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23-30,32-35 and 39-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This Office Action is responsive to the RCE filed 5/16/2008. Claim 23 is amended.

Claims 23-30, 32-35, and 39-41 remain pending and under prosecution.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. **Claims 23-28, 30, and 39-41** are rejected under 35 U.S.C. 103(a) as being unpatentable over Suydam in view of Dye (US Pat No. 3831446), further in view of Bortle (US Pat No. 4296502), even further in view of Nozaki et al (US Pat No. 6530909).

4. In regards to **Claims 23**, Suydam discloses a urological instrument comprising a number of consecutive components comprising at least a receiving member (34) for the urine flow and comprising a third component (30), in which, at least in a ready to use state, the receiving member is in open liquid communication with a urine guide (28) and an inlet of the third component, all best seen in Figure 2, characterized in that the instrument is embodied as a disposable article which is formed substantially from flexible material (i.e. plastic), in that the instrument is in a folded position in a storage state (¶0030), best seen in Figure 6, in that the instrument is in a straightened position in the ready to use state, as shown in Figure 2, said components of the instrument lying at least substantially in line with each other, in that the

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receiving member (34) has a relatively compact storage state and an expanded ready to use state (¶0031, 0040), in that the receiving member is designed and adapted to be brought manually from its storage state to its ready to use state, and that the receiving member is open on at least one side and comprises a cavity for receiving the urine flow therein, at least in its ready to use state, as best seen in Figure 2.

5. However, Suydam do not disclose said third component as a flow indicator means for assessing at least a magnitude of the urine flow. Dye teaches an analogous device comprising a flow indicator means (74) for assessing at least a magnitude of the urine flow, wherein said flow indicator means contributes to the calculation of flow rate by providing the volume of liquid and is thus considered as such (Col.5: 46-56). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Suydam to include a flow indicator means in the manner taught by Dye to improve the invention by supplying useful quantitative data for the urine received therein.

6. However, Suydam in combination with Dye do not disclose the components of the instrument lying at least substantially folded onto each other and substantially flush with each other. Bortle teaches an analogous device wherein the disposable components are folded such that said components lie at least substantially folded onto each other and substantially flush with each other, wherein “flush” is defined as “immediately adjacent” (www.dictionary.com), best seen in Figures 1-4, as an effective manner of compacting the components together into one disposable easy to carry package. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to replace the manner of folding the invention of Suydam as modified by Dye such that said components lie at least substantially folded onto each

other and substantially flush with each other, as taught by Bortle, as an equally as effective manner of folding the components to result in a compact easy to carry package that is adapted to brought into a ready-to-use state. It is noted that the term substantially is both broad and relative.

7. Suydam in combination with Dye and Bortle also do not explicitly disclose that when folded the respective external surfaces face each other. Nozaki et al disclose an analogous device comprising consecutive components 16, 9, 8, 4, 3, 2 that are folded onto each other with respective external surfaces facing each other and being substantially flush with each other, best seen in Figure 1 and 2, as an effective folding configuration that allows ease in manufacturing (Col.5: 1-5). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Suydam, Dye, and Bortle such that when folded the external surfaces of the components face each other as taught by Nozaki et al as an effective manner of folding that allows ease in manufacturing.

8. In regards to **Claim 24**, Suydam in combination with Dye, Bortle, and Nozaki et al disclose the invention described above including a collection device (26) that at least during use is in open communication with the urine guide (28) on an end opposite the receiving member (34), best seen in Figure 2, and the collection device is expandable from a relatively compact storage state to an expanded position of use. However, the combination does not disclose said collection device provided with a closing member having a normally closed position. Dye teaches the inclusion of a closing member, referred to as "valve means" (64), normally in the closed position, to allow controlled passage of fluid to an analogous collection device (24) (Col.5: 12-15). Therefore, it would have been obvious to one of ordinary skill in the art to

modify the collection device of Suydam as modified by Dye, Bortle, and Nozaki et al to include a closing member normally in the closed position, as taught by Dye, to provide a means for allowing the controlled passage of fluid from the collection device.

9. In regards to **Claim 25**, Suydam disclose the collecting device (26) is connected to an outlet of the flow indicator means (30), best seen in Figure 4.

10. In regards to **Claim 26**, Suydam discloses the collecting device (26) comprising a collecting bag, best seen in Figure 2.

11. In regards to **Claim 27**, Suydam in combination with Dye, Bortle, and Nozaki et al disclose the invention above but do not disclose the collecting device (26) provided with volume indicator means for a urine volume received therein. Dye teaches the use of volume indicator means, referred to as “graduated indicia” (74) (Col.5, line 45-47), to provide an effective means of determining total volume of urine collected. Therefore, it would have been obvious to one of ordinary skill in the art to modify the invention of Suydam as modified by Dye, Bortle, and Nozaki et al to include volume indicator means, as taught by Dye, to improve the device by providing an effective means to determine total volume.

12. In regards to **Claim 28**, Suydam discloses that in the storage state, at least one of the receiving member (34) and the collecting device (26) is capable of coving the urine guide (28) on one side of the flow indicator means (30).

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13. In regards to **Claim 39-41**, Suydam in combination with Dye, Bortle, and Nozaki et al disclose the invention above but do not disclose time duration indicator means. Dye teaches the use of time duration indicator means, referred to as “indicia” (62) and comprising a reservoir, referred to as "container" (24), which at least during use is in open communication via a defined passage opening, referred to as “chamber” (34) situated at least close to an inlet of a flow indicator means (38), with the urine flow (Col.4, line 42-52), wherein said reservoir is provided with volume indicator means, referred to as “graduated indicia” (74), for a urine volume received therein (Col.5, line 43-47), said time duration indicator means for determining a time duration of the urine flow (Col.5, line 2-7). Therefore, it would have been obvious to one of ordinary skill in the art to modify the invention of Suydam as modified by Dye, Bortle, and Nozaki et al to include time duration indicator means with the structure described above, as taught by Dye, to improve the device by including a means for determining a time duration of the urine flow.

14. **Claims 29-30** are rejected under 35 U.S.C. 103(a) as being unpatentable over Suydam in view of Dye, Bortle, and Nozaki et al, further in view of McWhorter (US Pat No. 3831453), even further in view of Persson (US Pat No. 3928875).

15. Suydam in combination with Dye, Bortle, and Nozaki et al disclose a urological instrument formed from flexible material, as explained above but do not disclose the flexible material comprising two foil sheets hermetically to each other on a mutual contact surface, at least partially forming one or more components of said device, wherein said components include the receiving member, the urine guide, the flow indicator means, and the collecting device.

16. McWhorter discloses a urological device formed from two flexible plastic sheets closed by heat, thus constituting a hermetic seal, forming one or more components of the device, in the instant case, a collection bag, referred to as “bag”(Col.1, line 51-61), for more accurate measurement of urine output (Col.1, line 22-23). However, McWhorter does not disclose the two flexible sheets as foil. Persson discloses a urine collector formed of flexible foil material for cheap manufacture and thus, disposability (Col.1, line 9-13).

17. Therefore, it would have been obvious to one of ordinary skill in the art to make the urological device of Suydam as modified by Dye, Bortle, and Nozaki et al using two sheets hermetically forming one or more components of said device, as taught by McWhorter, wherein said sheets are foil sheets, as taught by Persson, to effectively manufacture an accurate device while keeping costs cheap for economic disposal. As integral manufacture of the instrument components (such as the receiving member, urine guide, collecting device) is possible, it would then also be obvious to manufacture specific components of said urological device as separate from said foil sheets, for example, flow indicator means or time duration indicator means, for reasons such as better precision, as such methods of manufacture are obvious in view of McWhorter and known to those skilled in the art.

18. **Claim 32** is rejected under 35 U.S.C. 103(a) as being unpatentable over Suydam in view of Dye, Bortle, and Nozaki et al, further in view of Griffiths (US Pat No. 2856932).

19. Suydam in combination with Dye, Bortle, and Nozaki et al disclose a urological instrument but do not disclose said device provided with an irreparable breakable seal. Griffiths discloses a urethral catheter and bag maintained in a storage state, wherein the device is opened

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from a storage state to a ready-to-use state by breaking an irreparable breakable seal, referred to as “flag” (36), wherein the presence of an unbroken seal is an effective indicator of device sterility, best seen in Figures 2, 3, 5 (Col.3, line 56-62, 71-74). Therefore, it would have been obvious to one of ordinary skill in the art to incorporate a similar irreparable breakable seal as taught by Griffitts into the urological instrument disclosed by Suydam as modified by Dye, Bortle, and Nozaki et al for holding said instrument in the storage state, wherein the breaking of said seal brings the instrument into ready-to-use state, as an effective mean to indicate device sterility.

20. **Claim 33** is rejected under 35 U.S.C. 103(a) as being unpatentable over Suydam in view of Dye, Bortle, and Nozaki et al, further in view of Oxley (US Pat No. 5423792).

21. Suydam in combination with Dye, Bortle, and Nozaki et al disclose a urological instrument but do not disclose recording means arranged on an outer side for manual recording of indicator values determined with said device. Oxley discloses a fluid collection container having a recording means or identification element, in particular, a “writeable area” (42), for manual recording of information (Col.6, line 62-66). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include a similar recording means as taught by Oxley into the urological device of Suydam as modified by Dye, Bortle, and Nozaki et al to provide a means to effectively classify and identify said device.

22. **Claims 34-35** are rejected under 35 U.S.C. 103(a) as being unpatentable over Suydam in view of Dye, Bortle, and Nozaki et al, further in view of Oxley (US Pat No. 5423792), even further in view of LeVeen et al (US Pat No. 4532936).

23. Suydam as modified by Dye, Bortle, Nozaki et al, and Oxley disclose a urological instrument with a recording means but do not disclose the means as a removable self-adhesive label. LeVeen et al disclose urological data printed on self-adherent paper for ease of information transfer (Col.5, line 8-10). Therefore, it would have been obvious to one of ordinary skill to modify the recording means of Oxley to be a self-adhesive label, as taught by LeVeen et al, and incorporate that into the device of Suydam as modified by Dye, Bortle, Nozaki et al, and Oxley, to provide ease of urological information recording and transfer. Similarly, it would have been obvious to arrange such label at a position on said urological device such as at the position of a flow indicator means while leaving a transparent window for display of information.

Response to Arguments

24. Applicant's arguments with respect to the amendment to Claim 23 have been considered but are moot in view of the new ground(s) of rejection.

Applicant's arguments with respect to the combination of Suydam, Dye, and Bortle have been fully considered but they are not persuasive. Applicant contends that Suydam does not provide a flow indicator means or the components of the device folded onto each other in the storage state, that Dye does not disclose a foldable and disposable article, and that Bortle does not teach a flow indicator means. However, it seems from this that Applicant is merely attacking the references individually. In response to this it is noted that one cannot show nonobviousness by attacking

references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). It is also noted that Suydam already discloses a foldable article and to incorporate a component of Dye as motivated above into Suydam does not require Dye to be conceived as a foldable article. Furthermore, the flow indicator that Dye is used to teach is simply indicia 74 as elaborated above, and when incorporated into the invention of Suydam such as on funnel 28, it would be obvious to one of ordinary skill in the art how to fold said funnel and thus said flow indicator as discussed above, considering that Suydam already discloses a foldable device.

3. Thus in light of the specific teachings of Suydam, Dye, Bortle, and Nozaki et al as elaborated in the rejection above, Suydam, Dye, Bortle, and Nozaki et al teach the urological measuring instrument comprising a receiving member, flow indicator means, and urine guide in communication with each other in the above manner, all configured to be in a folded position in a storage state with the components lying at least substantially folded onto each other with respective external surfaces facing each other and substantially flush with each other, as motivated by the reasons explained above. As already noted, Applicant is reminded that the term substantially is both relative and broad.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HELEN NGUYEN whose telephone number is (571)272-8340. The examiner can normally be reached on Monday - Friday, 9 am - 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. N./
Examiner, Art Unit 3736

/Brian Szmaj/
Patent Examiner, Art Unit 3736